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| 09/982,474      | 10/17/2001  | Wilhelmus Theodorus Antonius Maria De Laat | 246152012710        | 8056             |

25225 7590 03/21/2005

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EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/982,474

**Applicant(s)**

DE LAAT ET AL.

**Examiner**

Randall Winston

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,15,16,19,20 and 36-64 is/are pending in the application.
- 4a) Of the above claim(s) 38-51 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,15,16,19,20,36,37 and 52-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Acknowledgement is made of the receipt and entry of the Request for Continued Examination (RCE) on 12/20/2004.

Examiner has acknowledged that claims 38-51 and 64 have been withdrawn and claims 2, 9-14, 17-18 and 21-35 have been cancelled.

Newly amended claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 52 are rendered vague and indefinite because of the phrase "in a fermentation medium consisting essentially of chemically defined constituents wherein the amount of complex carbon and/or nitrogen." The above phrase is confusing because on one hand the specification states that the claimed fermentation medium consisting essentially of chemically defined constituents should not contain no complex raw material. However, in applicant claims of 1 and 52, the fermentation medium contains complex carbon and/or nitrogen source. Clarification is deemed necessary of should the fermentation medium contain complex material such as carbon and/or nitrogen or should the fermentation medium contain no complex material.

Claims 1 and 52 recite the limitation "complex carbon and/or nitrogen source."

There is insufficient antecedent basis for this limitation in the claims.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan (US 4164445) in view of Microbiology, fourth edition, Pelezar, Reid, and Chan pages 853-856.

Although unclear as drafted, applicant claims a process for the production of Beta-Lactam (i.e. Penicillin V and/or Adipoyl-7-ADCA) comprising the steps of fermenting on a volume scale of at least 10 m<sup>3</sup> a microbial strain (e.g. *Pencillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium consisting essentially of chemically defined constituents wherein the chemically defined constituents are an amount of complex carbon and/or nitrogen source is at most 10% of the total amount of carbon and/or nitrogen and recovering the Beta-Lactam from the fermentation medium is apparently claimed. (see, the 112, 2<sup>nd</sup>, rejection above).

Sheehan et al. (see, e.g. abstract, column 1 lines 5-19, column 2 lines 14-18 and example and example 2) teach a process for the production of Beta-Lactam (i.e. Penicillin V) comprising the steps of fermenting a microbial strain (e.g. *Pencillium chrysogenum*) that produces a Beta-Lactam in a fermentation medium consisting essentially of chemically defined constituents wherein the chemically defined constituents are complex carbon (i.e. ethanol) and/or nitrogen source (i.e. ammonium salt).

Sheehan et al. do not teach the process of the production of Beta-Lactam comprising the steps of fermenting on a volume scale of at least 10m<sup>3</sup>, the claimed process which produces adipoyl-7-ADCA, the amount of complex and/or nitrogen is at most about 10 %, and recovering the Beta-Lactam from the fermentation medium.

Microbiology, pages 853-856, teaches that a Beta-Lactam (penicillin) was the first antibiotic to be produced industrially utilizing a similar standard chemically defined medium as the claimed invention's chemically defined medium (see, especially, e.g. page 855-856, the steps).

It would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Sheehan et al.'s teaching and to include the beneficial teachings of Microbiology because the above two combined reference teachings utilizing the same process steps would produce an improve process for the production of Beta-Lactam at an industrialized scale. The adjustment of these and other conventional working conditions (i.e. fed-batch fermentation, the amount of complex and/or nitrogen is at most about 10 %, recovering the Beta-Lactam from the

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fermentation medium and the substitution of one Penicillin for the another Penicillin (i.e. the substitution of Penicillin V for adipoyl-7-ADCA) utilizing the same claimed steps)), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is 703-305-0404. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3110.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



CHRISTOPHER R. TATE  
PRIMARY EXAMINER